REMARKS

Claims 14, 21, 22, 23, 24, 25, 26, 27, 28, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48 and 49 are pending in the instant application. Claims 14, 21, 22, 23, 24, 25, 26, 27, 28, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48 and 49 have been rejected. Claims 14, 24, 28, 38, 39, 40, 44, 45 and 46 have been amended. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments, the following remarks and the Declaration by Dr. Patrick Sluss provided herewith.

I. Rejection of Claims under 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph

The rejection of claims 14, 21-28 and 35-49 under 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph, has been maintained. The Examiner suggests that the claimed invention is not supported by either a substantial utility or a well established utility. More specifically, the Examiner suggests that the specification does not teach the protein sequence or the open reading frame of SEQ ID NO:1. The Examiner therefore suggests that the specification does not provide enough information to indicate for which

proteins the claimed antibodies are specific. The Examiner suggests that the specification does not describe a utility for antibodies with unknown specificity.

Applicants respectfully traverse this rejection.

MPEP 2164.01 is clear; any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable **one skilled in the pertinent art** (emphasis added) to make and use the claimed invention.

MPEP 2107 is also clear; an invention has a well-established utility if (i) **a person of ordinary skill in the art** (emphasis added) would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g. properties or applications or a product or process), and (ii) the utility is specific, substantial and credible.

The instant specification clearly meets these requirements of enabling how to use and establishing a specific, substantial and credible utility with respect to

the instant claimed invention to one skilled in the pertinent art.

Applicants are submitting herewith a Declaration by Dr. Patrick Sluss, one clearly skilled in the pertinent art. See paragraphs 1 through 3 of Dr. Sluss' Declaration.

Dr. Sluss reviewed the instant patent application as well as the Office Action mailed October 22, 2007. See paragraph 4 of Dr. Sluss' Declaration.

Dr. Sluss disagrees with the Examiner that utility of antibodies for a diagnostic cancer marker expressed by a defined nucleic acid such as SEQ ID NO:1 is dependent upon identification of "the" protein sequence or the open reading frame. See paragraph 4 of Dr. Sluss' Declaration.

Instead, after review of the instant application and in particular data presented in Examples 1 and 2 of the patent application relating to mRNA overexpression of Ovr110, Dr. Sluss believe Ovr110 to be useful as a diagnostic marker for gynecologic cancers. See paragraph 5 of Dr. Sluss' Declaration.

Thus, based upon properties of the nucleic acid sequences taught in the instant specification, a skilled

artisan was able to immediately appreciate why the invention is useful.

The Court of Appeals for the Federal Circuit has made clear that usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. In re Brana 51 F.3d. 1560, 34 USPQ2d 1436 (Fed. Cir. 1995).

Also clear from Dr. Sluss' Declaration is that the "further research and development" included to select antibodies useful as diagnostic cancer markers for a diagnostic marker such as Ovr110 was well established and routine by 1998. See paragraphs 6 and 7 of Dr. Sluss' Declaration.

Specifically, as of 1998 generating proteins and peptides encoded by a defined nucleic acid such as SEQ ID NO:1 or its fragments was routine. See paragraph 6 of Dr. Sluss' Declaration. Further, there were a number of computer programs routinely used as of 1998 to identify potential open reading frames and deduced proteins and peptides expressed by a defined nucleic acid sequence such

as SEQ ID NO:1 or its fragments. See paragraph 6 of Dr. Sluss' Declaration.

Also routine as of 1998 was to utilize the generated proteins and peptides encoded by a defined nucleic acid sequence such as SEQ ID NO:1 or its fragments to make antibodies. See paragraph 7 of Dr. Sluss' Declaration. Antibodies were then routinely selected for their ability to detect cancer. See paragraph 7 of Dr. Sluss' Declaration.

As discussed in Dr. Sluss' Declaration at paragraph 7 and 8, once a nucleic acid sequence such as SEQ ID NO:1 or its fragments is associated with a utility such as an ovarian cancer diagnostic, there were several approaches available as of 1998 to generate antibodies that could be used to formulate tests for circulating proteins originating from the specified nucleic acid sequence. According to Dr. Sluss, it is the teaching in the instant patent application, that this sequence, and the other sequences revealed by the "ovary specific gene" approaches described, is associated with ovarian cancer that focuses the well established routine work needed to then generate

and validate antibody-based diagnostic methods that utilize the coded proteins as biomarkers for ovarian cancer.

Thus, clear from Dr. Sluss' Declaration is that the instant specification contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. Also clear from Dr. Sluss' Declaration is that a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics disclosed in the instant specification.

Applicants have amended claims 14, 24, 28, 38, 39, 40, 44, 45 and 46 to be drawn to an isolated antibody or antibody fragment that binds specifically to a protein encoded by polynucleotide sequence SEQ ID NO:1 or to a fragment of a protein encoded by polynucleotide sequence SEQ ID NO:1, and methods for use thereof.

As evidenced by Dr. Sluss' Declaration, teachings of the instant specification meet the utility requirements of 35 U.S.C. 101 and the enablement requirements of 35 U.S.C. 112, first paragraph with respect to the instant claimed invention.

Withdrawal of these rejections is therefore respectfully requested.

II. Rejection of Claims under 35 U.S.C. 112, first paragraph - Written Description

Claims 14, 21-28 and 35-49 also remain rejected under 35 U.S.C. 112, first paragraph for failing to meet the written description requirement. The Examiner suggests that the specification does not teach the protein sequence or the open reading frame of SEQ ID NO:1. The Examiner thus suggests that the specification does not provide enough information to indicate for which proteins the claimed antibodies are specific. The Examiner suggests that without identifying for which protein the claimed antibodies are specific, the antibodies lack a written description as the specification does not disclose identifiable structural or functional attributes of said antibodies.

Applicants respectfully traverse this rejection.

The Court of Appeals for the Federal Circuit has held that as long as **the skilled artisan** would have understood the inventor to be in possession of the claimed invention at the time of filing, every nuance of the claims need not

be explicitly described in the specification to meet the written description. Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991).

As discussed in Section II, supra, Applicants are submitting herewith a Declaration by Dr. Patrick Sluss. As evidenced by paragraphs 1 through 3 of Dr. Sluss' Declaration, he is highly skilled in the pertinent art.

Contrary to the Examiner's suggestion, Dr. Sluss does not believe that identification of a protein sequence or an ORF in the patent application is required for one of skill to identify structural or functional attributes of antibodies to proteins or peptide fragments of a defined nucleic acid sequence such as SEQ ID NO:1 or fragments thereof. See paragraph 8 of Dr. Sluss' Declaration. Instead, the nucleic acid sequences contain all the information needed for one skilled in the art to predict all proteins that could be coded using software tools available in 1998. See paragraph 8 of Dr. Sluss' Declaration. These protein sequences could then be used in homology searches to identify target immunogens for specific antibody generation, again using software tools as well as databases available in 1998. See paragraph 8 of

Dr. Sluss' Declaration. Further, antigenic epitope modeling could be used on the predicted sequences to identify small immunogens easily synthesized and used to produce panels of site specific monoclonal antibodies. See paragraph 8 of Dr. Sluss' Declaration. Antibodies could then be routinely selected for recognition of endogenous protein products of the nucleic acid sequences taught in the patent application. See paragraph 8 of Dr. Sluss' Declaration.

Thus, disclosure of every nuance of the claims, including the protein sequence or open reading frame of SEQ ID NO:1, was not required for a skilled artisan to understand the inventor's possession of antibodies based upon teachings of the instant specification.

The Court of Appeals for the Federal Circuit has also held that for most technologies which are mature, and wherein the knowledge and level of skill in the art is high, a written description question should not be raised for original claims even if the specification discloses only a method of making the invention and the function of the invention. See, e.g. In re Hayes Microcomputer

Products, Inc. Patent Litigation, 982 F.2d 1527, 1534-1535, 25 USPQ2d 1241, 1246 (Fed. Cir. 1992).

Antibodies were set forth in the original claims.

Further, clear from Dr. Sluss' Declaration is that the art of antibody production was mature as of 1998 with many routinely used tools available to the skilled artisan. Also clear from Dr. Sluss' Declaration is that it is the identification of SEQ ID NO:1 and its associated fragments by the inventors to be associated with ovarian cancer that focuses the well established routine work needed to then generate and validate antibody-based diagnostic methods that utilize the coded proteins as biomarkers for ovarian cancer.

Thus, a specific teaching of the protein or open reading frame was not required for a skilled artisan to understand the inventor to be in possession of the claimed invention at the time of filing and to meet the written description requirements with respect to the instant claimed invention.

Withdrawal of this rejection is therefore respectfully requested.

III. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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